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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of: **KOHNO, Naoyuki, et al.**

Group Art Unit: 1645

Serial No.: **10/585,985**

Examiner: Not Yet Assigned

Filed: **July 13, 2006**

P.T.O. Confirmation No.: 1712

For: **PROTEIN IMMOBILIZATION METHOD AND QUANTIFICATION METHOD**

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Date: October 20, 2006

Sir:

The attention of the Patent and Trademark Office is hereby directed to a copy of the PCT  
Notification of Transmittal of Copies of Translation of the International Preliminary Report on  
Patentability attached herewith.

This Report is submitted herewith to be placed in the U.S. Patent and Trademark Office  
file of this case.

Respectfully submitted,

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**23850**  
PATENT TRADEMARK OFFICE

Enclosure: PCT Notification of Transmittal of Copies of Translation of the International Preliminary  
Report on Patentability

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

WAKO PURE CHEMICAL INDUSTRIES, LTD.  
1-7, Nihonbashi-honcho 2-chome, Chuo-ku Tokyo  
1030023  
JAPON

Date of mailing (day/month/year) 31 August 2006 (31.08.2006)	
Applicant's or agent's file reference F1590WAKOPAT	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP2005/000737	International filing date (day/month/year) 21 January 2005 (21.01.2005)
Applicant WAKO PURE CHEMICAL INDUSTRIES, LTD. et al	

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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## **PATENT COOPERATION TREATY**

PCT

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>F1590WAKOPAT</b>	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. <b>PCT/JP2005/000737</b>	International filing date ( <i>day/month/year</i> ) <b>21 January 2005 (21.01.2005)</b>	Priority date ( <i>day/month/year</i> ) <b>21 January 2004 (21.01.2004)</b>	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant <b>WAKO PURE CHEMICAL INDUSTRIES, LTD.</b>			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

<p>The International Bureau of WIPO  34, chemin des Colombettes  1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report  22 August 2006 (22.08.2006)</p> <p>Authorized officer</p> <p><b>Yoshiko Kuwahara</b></p> <p>e-mail: <a href="mailto:pt07@wipo.int">pt07@wipo.int</a></p>
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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

**TRANSLATION**

PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>F1590WAKOPAT</b>		Date of mailing (day/month/year)	
International application No. <b>PCT/JP2005/000737</b>	International filing date (day/month/year) <b>21.01.2005</b>	Priority date (day/month/year) <b>21.01.2004</b>	
International Patent Classification (IPC) or both national classification and IPC			
Applicant <b>WAKO PURE CHEMICAL INDUSTRIES, LTD.</b>			

<p>1. This opinion contains indications relating to the following items:</p> <p> <input checked="" type="checkbox"/> Box No. I Basis of the opinion  <input type="checkbox"/> Box No. II Priority  <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI Certain documents cited  <input type="checkbox"/> Box No. VII Certain defects in the international application  <input type="checkbox"/> Box No. VIII Certain observations on the international application         </p>
<p>2. <b>FURTHER ACTION</b></p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000737

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language

, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing

table(s) related to the sequence listing

b. format of material

in written format

in computer readable form

c. time of filing/furnishing

contained in the international application as filed.

filed together with the international application in computer readable form.

furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT / JP2005/000737

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																									
<p>1. Statement</p> <table> <tr> <td>Novelty (N)</td> <td>Claims</td> <td>6, 11, 14-34</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td>1-5, 7-10, 12, 13</td> <td>NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims</td> <td></td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td>1-34</td> <td>NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims</td> <td>1-34</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td></td> <td>NO</td> </tr> </table>			Novelty (N)	Claims	6, 11, 14-34	YES		Claims	1-5, 7-10, 12, 13	NO	Inventive step (IS)	Claims		YES		Claims	1-34	NO	Industrial applicability (IA)	Claims	1-34	YES		Claims		NO
Novelty (N)	Claims	6, 11, 14-34	YES																							
	Claims	1-5, 7-10, 12, 13	NO																							
Inventive step (IS)	Claims		YES																							
	Claims	1-34	NO																							
Industrial applicability (IA)	Claims	1-34	YES																							
	Claims		NO																							
<p>2. Citations and explanations:</p> <p>(Documents)</p> <p>Document 1: Concaves, C.A. et. al., "Electrotransfer of fixed phosphoproteins from pieces of dried polyacrylamide gel to small disks of nitrocellulose, nylon or polyvinylidene difluoride" ELECTROPHORESIS, (1993), Vol. 14, No. 8, pages 789 to 793</p> <p>Document 2: Jacobson, G. et al., "Important parameters in semi-dry electrophoretic transfer" ELECTROPHORESIS, (1990), Vol. 11, No. 1, pages 46 to 52</p> <p>Document 3: Sheffield, J.B., et al., "A solid-phase method for the quantitation of protein in the presence of sodium dodecyl sulfate and other interfering substances" ANALYTICAL BIOCHEMISTRY, (1987), Vol. 166, No.1, pages 49 to 54</p> <p>Document 4: Yamaguchi, K. et al., "Immunostaining method of isoferritins separated by isoelectric focusing on cellulose acetate membrane" JAPANESE JOURNAL OF ELECTROPHORESIS, (1991), Vol. 35, No. 4, pages 275 to 277</p> <p>Document 5: JP, 58-205855, A (Tokyo Biochemical Research Foundation), 30 November, 1983 (30.11.83)</p> <p>Document 6: JP, 2002-236127, A (Joko Co., Ltd.), 23 August, 2002 (23.08.02)</p> <p>Document 7: WO, 02/057793, A2 (Baxter International Inc.), 25 July, 2002 (25.07.02) (Explanation)</p> <p>1. Concerning Novelty (Claims 1-5, 7-10, 12 and 13)</p> <p>Documents 1 and 2 describe a method using a solvent containing SDS and methanol as a method for fixing a protein on a carrier such as nitrocellulose or PVCF for quantitative measurement by a method such as immunoblotting. Particularly, in document 2, a solution of 20% methanol and 0.1% SDS is used.</p> <p>Accordingly, the subject matters of claims 1-5, 7-10, 12 and 13 do not appear to be novel.</p> <p>2. Concerning Inventive Step (Claims 6, 11 and 14-34)</p> <p>Documents 3 and 4 describe that methanol is used for fixing a protein on a carrier such as nitrocellulose or PVDF. Documents 4-6 describe that trichloroacetic acid (TCA) that is a type of halogen carbonic acid is used for fixation of a protein.</p> <p>Since methanol and trichloroacetic acid are reagents having similar functions, a person skilled in the art could easily use these reagents in combination. A person skilled in the art could</p>																										

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INTERNATIONAL SEARCHING AUTHORITY

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Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

accordingly set the amount of each reagent.

In the specification, comparison tests for various kinds of proteins are conducted for the resulting effects, but the carrier used is a PVDF film alone. In this point, it is common general technical knowledge that the fixation effect of the fixation reagent varies depending on the carrier used, but in the claims, it is only specified as a solid phase having a hydrophobic surface. Thus, carriers other than those using a film composed of nitrocellulose, PVDF or the like are not found to have a noticeable effect.

Thus, the subject matters of claims 6 and 11 do not appear to involve an inventive step.

Further, as described in document 7, a method of fixing an aberrant form prion protein and detecting/quantitatively measuring the protein by immunoblotting is known, and therefore a person skilled in the art could easily perform fixation and detection/quantitative measurement using the aforementioned mixed solvent. The effect thereof is not found to be noticeable except for effects for specific film carriers.

Thus the subject matters of claims 14-34 do not appear to involve an inventive step.

3. Industrial Applicability

The subject matters of claims 1-34 appear to be industrially applicable.